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PRESS RELEASE

**Independent experts from
World Health Organisation report
on NICE technology appraisals**

The World Health Organization (WHO), the United Nations specialised agency for health, has today provided the results of their independent peer review of the NICE technology appraisal programme. The report is to be presented to the Institute's Board at its public meeting in Wrexham.

The review was undertaken by a panel of international experts who assessed the Institute's work in developing guidance on the use of medicines and devices, against the highest international criteria for quality. The Review Team focussed their report on areas where there is controversy or potential for improvement. They have given their opinion on the work of NICE and made a number of recommendations.

Kees de Joncheere, Regional Advisor for Health Technology and Pharmaceuticals in the WHO regional office for Europe said "Following our detailed work we concluded that, in only four years, NICE has developed a well-deserved reputation for innovation and methodological developments that represent an important model for technology appraisals internationally. The Review Team was impressed by the Institute's commitment to using rigorous methodology throughout the process of technology assessment".

He commented, "Published NICE appraisals are already being used as international benchmarks - an obvious recognition of their credibility"

He added “As a team we focussed on areas of controversy or potential improvement and we have been able to make a number of recommendations to the NICE Board.

For example:

- We recognise that NICE has set new standards in the consideration of stakeholder inputs and transparency, including the provision of documents and information, via the NICE web site. However to gain access to key information NICE also accepts material designated as confidential. In the main this comes from the pharmaceutical industry. Whilst we welcome the steps they have taken to push these boundaries with the Industry, NICE should reconcile this inherent contradiction. We encourage NICE to use its leverage to further advance transparency in this area which would also be of international benefit.
- NICE needs to make it clearer that the membership of the Appraisal Committee is based on skills in and knowledge about evidence appraisal and judgement rather than representation of particular interests.
- In addition we have recommended a number of process points - NICE should develop a handbook on the preparation of assessment reports and the consultees’ meeting should become a formal ‘Preliminary Exchange of Evidence’, at which time all stakeholders should be asked to provide details of what they propose to submit. Only in extraordinary circumstances should they accept information over and above that declared for submission by the stakeholders at this meeting. And it should be a requirement that stakeholder submissions be lodged as soon as possible after the start of the assessment process.
- NICE should also review the timeframes for the assessment and appraisal process so that the current time pressures, at the end of the assessment report period and early appraisal period, are reduced and more time is allowed for critical evaluation of consultees’ comments. However this does not necessarily mean that the overall timeline should be increased.
- Finally NICE is in the process of developing explicit criteria for use in decision-making. These will be consistent with the broad principles that were defined with the establishment of NICE. This represents a significant development internationally and may lead to important advances in knowledge within the field of health technology assessment. NICE should continue this work to develop a decision-making system in order that it can specify the weight that is

placed on clinical evidence, economic evidence and other factors, such as equity and social values.”

Professor Sir Michael Rawlins, Chair of NICE, said: “The Institute is immensely grateful to WHO and the members of the international review team for conducting this review so thoroughly. The Board is gratified that, overall, the report considers that NICE's approaches and methodologies are robust; and that NICE's reputation ‘for innovation and methodological developments’ is well-deserved. The report makes helpful suggestions about how our processes and procedures might be enhanced, and the Board will give this careful consideration. The Institute will take the WHO recommendations into account in its current review of appraisal process and methodology”.

Ends

Notes to Editors

The full WHO report is published on the NICE web site.
(<http://www.nice.org.uk/Docref.asp?d=85797>).

About the NICE review of Appraisals (referred to in Sir Michael’s quote)

1. NICE is conducting its regular review of the technology appraisal process and methodologies. On the 4th August NICE published two consultation documents which outline potential changes to the methodology and process that underpin the NICE technology appraisal work programme. Consultation will close on the 26th September 2003. The report produced by the World Health organisation will be fed into this work.
http://www.nice.org.uk/pdf/2003_034_Consultation_on_appraisal_process.pdf

About the WHO Review

2. **Why was the review initiated?** – Last year’s House of Commons’ Health Select Committee report on the work of NICE recommended an independent detailed peer review of the Institute’s work. In response to this recommendation NICE invited WHO to undertake an independent review.
3. **What were the terms of reference?** Terms of reference – with reference to established and credible processes and methodologies, the review should test:
 - the consistency of the outcome of the appraisal with conclusions reached on the same topics by reputable scientific groups outside the UK.
 - the scientific and methodological rigor of the health technology assessment reports used by the Appraisal Committee;
 - the utility of the other components of the evidence base, including submissions from manufacturers, patient organizations and professional groups;
 - the suitability of the processes used to assemble and interpret evidence and to engage with stakeholders during the appraisal;

4. **Which topics were looked at?** The experts considered four recently published technology appraisals in order to assess the scientific robustness of the process and methodology used by the Institute to prepare its guidance. These were tested against an international stage. The appraisals considered were:
- etanercept and infliximab for the treatment of rheumatoid arthritis (no 36, March 2002): <http://www.nice.org.uk/cat.asp?c=35993>
 - newer (atypical) antipsychotic drugs for the treatment of schizophrenia (no 43, June 2002): <http://www.nice.org.uk/cat.asp?c=32878>
 - imatinib (Glivec) for chronic myeloid leukaemia (no 50, October 2002): <http://www.nice.org.uk/cat.asp?c=37604>
 - ultrasound locating devices for placing central venous catheters (no 49, September 2002): <http://www.nice.org.uk/cat.asp?c=36752>.
5. **Who was on the review team?** The review was performed by a team of five international experts:
- Dr Suzanne Hill (Coordinator of Team), Senior Lecturer and Head of Discipline Clinical Pharmacology at the University of Newcastle, Australia. Technical expert advisor to the Pharmaceutical Benefits Advisory Committee, Australia.
 - Silvio Garattini MD, Istituto di Ricerche Farmacologiche 'Mario Negri', Milan, Italy. Member of Committee for Proprietary Medicines Products of European Agency for the Evaluation of Medicines
 - Jos van Loenhout MD PhD, Senior Medical Advisor to the Reimbursement Committee of the Dutch Healthcare Insurance Board ,Diemen, The Netherlands.
 - Bernie J O'Brien, PhD, Professor, Dept Clinical Epidemiology and Biostatistics, McMaster University, Canada, Member, Economics Sub-Committee of the Drug Quality and Therapeutics Committee for Ontario
 - Kees de Joncheere , Regional Adviser for Health Technology and Pharmaceuticals WHO Regional office for Europe
6. **When did the review happen and what did they look at?** The WHO experts carried out their review during June and July 2003. They reviewed documents associated with the technology appraisal guidance, conducted a series of interviews, met those directly involved in the interpretation of the evidence, and compared NICE recommendations to the international stage.

About NICE

7. NICE is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care for those using the NHS in England and Wales. Its guidance is for healthcare professionals and patients and their carers to help them make decisions about treatment and healthcare. For further information about NICE you can visit www.nice.org.uk.
8. NICE produces guidance in three areas of health:
- the use of new and existing medicines and treatments within the NHS in England and Wales – technology appraisals.
 - the appropriate treatment and care of patients with specific diseases and conditions within the NHS in England and Wales – clinical guidelines.
 - whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use– interventional procedures.

NICE also funds three enquiries that undertake research into the way patients are treated to identify ways of improving the quality of care (the investigations are known as confidential enquiries).

9. NICE guidance and recommendations are prepared by independent groups that include professionals working in the NHS and people who are familiar with the issues affecting patients and carers.

About the World Health Organisation

The World Health Organization, the United Nations specialised agency for health, was established in 1948. WHO's objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health. Health is defined in WHO's Constitution as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. the Regional office for Europe is located in Copenhagen and for more information you can visit <http://www.who.dk/eprise/main/WHO/Home/TopPage>

10. In carrying out its activities, WHO's secretariat focuses its work on the following six core functions:

- Articulating consistent, ethical and evidence-based policy and advocacy positions.
- Managing information by assessing trends and comparing performance; setting the agenda for, and stimulating research and development.
- Catalysing change through technical and policy support, in ways that stimulate cooperation and action and help to build sustainable national and inter-country capacity.
- Negotiating and sustaining national and global partnerships.
- Setting, validating, monitoring and pursuing the proper implementation of norms and standards.
- Stimulating the development and testing of new technologies, tools and guidelines for disease control, risk reduction, health care management, and service delivery.